

METHODS OF DEVELOPMENT OF A SYMPTOM AND QUALITY OF LIFE ASSESSMENT FOR BOWEL SYMPTOMS INCLUDING ANAL INCONTINENCE – ICIQ-BS

Hypothesis / aims of study

Under the aegis of the International Consultation on Incontinence, whose scientific programmes are organised by the ICS, the ICI Modular Questionnaire (ICIQ) project (www.iciq.net) is developing a comprehensive and universally applicable modular questionnaire for the assessment of a variety of pelvic symptoms, including those of the lower urinary tract, lower bowel and vagina. There are currently no questionnaires that have been sufficiently validated, to adequately measure symptoms and quality of life (QoL) associated with bowel symptoms including anal incontinence (1). The ICIQ-BS intends to address this issue, incorporating various methods at the design stage to improve inclusion of all items of importance to both clinicians and patients. Clinician involvement is essential in order to capture the symptom areas that may be indicative of a functional abnormality. However, although clinicians may be the best observers of the outward manifestations of a trait or disorder, only those who experience it can report on the more subjective elements (2). It is now widely acknowledged that patient involvement should form a fundamental aspect in the development of quality of life measures.

Study design, materials and methods

Literature searches were carried out to identify all published questionnaires designed for use in this condition area. Systematic review was conducted according to a number of criteria, including intended population, domains assessed and the specific questions included. All questionnaire items were formulated into an intuitive list and sub-grouped into the following basic domains: upper gastrointestinal, incontinence-specific, bowel storage, bowel evacuation and impact items. Expert opinion was sought from clinical experts in the field as to relevant and appropriate items for such an assessment tool.

In order to develop the ICIQ-BS from a patient-centred perspective, analysis of free-text written comments gathered from patients completing a symptom questionnaire at baseline and following biofeedback treatment for anal incontinence, was undertaken. Symptom items in this questionnaire addressed frequency, urgency, ability to delay, stool form, incontinent episodes, amount of leakage, flatus control and pad usage. Patients were asked to describe in "what way" their life was restricted, if at all, due to their bowel problems. Content analysis (3) was employed to identify apparent themes. Response frequencies were calculated as proportions of overall comments to identify areas of greater perceived restriction. Proportions of question items addressing these issues were also calculated from the total set of QoL items, in order to indicate the importance placed on these areas by existing questionnaires. Expert feedback was summarised, and comparisons were made between patients' free text responses and existing questionnaire items, in order to inform the development of the ICIQ-BS questionnaire. Ethics approval was granted by Harrow Local Research Ethics Committee for this study.

Results

Clear areas of consensus were reached from clinicians' feedback. In particular, it was indicated that a questionnaire to assess lower bowel symptoms and anal incontinence would not need to address upper gastrointestinal symptoms. Items to assess type, amount and frequency of incontinent episodes were deemed essential with additional evaluation of passive and urgency type incontinence. Ability to delay, urgency and the duration that symptoms had been experienced were also reported to be central to the assessment of bowel symptoms. An attempt to define bowel habit according to individual patients was recommended in order to provide a complete review of the condition. Straining and incomplete evacuation were considered other important symptoms.

The free text field responses from the questionnaires were completed by 420 patients (359 females, 61 males, mean age 53.96 years, range 15 to 86 years). 284 (68%) of these made

comments relating to perceived restriction on life due to their bowel problems. The most prominent theme identified was the importance of toilet location. Preventative measures were also commonly quoted with prevention by dietary changes excluded. Typical comments included the following: "...especially in the mornings, unless I go at least twice I do not leave the house". The areas of greatest consistency and disparity between patients' free text comments and existing question items, compared as overall proportions, are displayed in Table 1 below.

Table 1: Comparison of patients' free text responses regarding restriction caused by bowel symptoms, with existing questionnaire assessment items

Impact category	Proportion of overall comments (%)	Proportion of total QoL items (%)
Working life	4	3
Hygiene/Odour	8	8
Relationships	1	1
Toilet location	10	2
Fear	9	1
Preventative measures	6	0
Embarrassment	4	0
Bowel unpredictability	3	0

Interpretation of results

Clinician feedback served to define the most important areas for assessment of lower bowel symptoms including anal incontinence. However, patients' free text responses highlighted inconsistencies between important matters for patients and current questionnaire items, with particular relevance to issues such as toilet location, fear, preventative measures, embarrassment and bowel unpredictability.

These results indicate that if patient input is not included when developing questionnaire content, these areas that affect QoL could easily be overlooked. Especially important is the assessment of preventative measures, as strategies developed by patients to cope with their symptoms may lead the clinician to underestimate the true severity of their condition. In-depth patient interviews are needed to further explore the issues raised before proceeding to essential psychometric evaluation. These steps are currently being undertaken to further develop the ICIQ-BS.

Concluding message

Several questionnaires have been developed to assess symptom severity and impact on QoL in patients with bowel symptoms and anal incontinence but have not employed the extensive patient-based methodology described above (3). This has resulted in areas of disparity between what patients report as their greatest restrictions to life and the questions used in existing measures. It is intended that the ICIQ-BS will address this inconsistency and provide a comprehensive and psychometrically robust measure of patients' symptoms and the impact these have on their quality of life, as defined by both clinicians and the patients themselves.

References

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- (3) 1992. Questionnaire design, interviewing and attitude measurement. New edition. London: Pinter publishers Ltd.

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